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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,730	10/19/2001	Paul Arthur Mason	10071-018-999	9664

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,730	MASON, PAUL ARTHUR	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,12-16,22,24-27,55,56 and 59-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,12-16,22,24-27,55,56 and 59-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE under 1.114, both filed 12/15/2004.

Claims 2, 7-11, 17-21, 23, 28-54, 57, and 58 have been canceled, and claims 62-69 have been added.

Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2005 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "about" does not set forth the metes and bounds of the amounts recited in the claims. Recourse to the specification does not define the expression in order to provide an indication as what ranges of specific amounts of the ingredients are covered by the term "about".

Claim 56 is in an improper dependent form as it not only fails to further limit the subject matter of a previous claim 1, but it broadens the scope of claim 1. Claim 56 recites from 0.5 to 20% of local anesthetic, while claim 1 recites the specific range 10% of local anesthetic.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,383,511 ('511).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '511 teaches non-invasive method for intradermal prevention or amelioration of pain from closed wound and cut wound (abstract; col.3, lines 30-32). The method comprises application to the skin of a patch comprising local anesthetic, most preferably lidocaine (col.3, lines 40-45, 55-67). The patch is sterile as implied by the teaching of the reference that the patch is applied using sterile technique (col.5, lines 5-7). The patch comprises drug containing layer comprises polyvinylpyrrolidone hydrogel, from 1-25% local anesthetic and preservative; and a breathable backing of polyester (col.5, lines 40-48, 65-67; col.6, lines 63-65; col.7, lines 3-10, 45-49; col.8, lines 27-30).

US '511 does not teach the amount of the PVP in the hydrogel, or the specific preservatives.

The amount of PVP does not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '511 and select the amount of the PVP according to the desired adhesiveness of the patch depending on the anatomical site of application, with reasonable expectation of the delivered patch in ameliorating pain at the site of application.

6. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '511 in view of US 5,143,071 (071).

The teachings of US '511 are discussed above.

US '511 does not teach the amount of the PVP in the hydrogel, or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59). The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '511 and select the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

7. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being obvious over 6,455,066 ('066) in view of US '071.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an

invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '066 teaches patch comprising permeable backing (breathable), and a carrier formulated with at least one local anesthetic (col.8, lines 4-6; col.9, lines 11, 18, 64-65). The carrier comprises polyvinyl pyrrolidone hydrogel (col.8, lines 27-28; 67). The preferred local anesthetic is lidocaine (col.5, lines 30-39). The formulation comprises preservatives (col.6, line 57). The backing is polyester (col.9, lines 12-13). The patch is used for local anesthetization of skin prior to minor surgical procedures (col.11, lines 28-29). The anesthetic forms 0.5 to 12% of the formulation (col.9, lines 64-67).

US '066 does not teach the amount of the PVP in the hydrogel, the patch is sterile, or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59). The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '066 and select the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

8. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,469,227 (227) in view of US '071.

US '227 teaches a non-occlusive adhesive skin patch used to relieve topical discomfort (abstract; col.2, lines 5-8). The patch comprises a breathable backing of polyester coated with a therapeutic formulation (col.3, lines 7-16, 35-36, 42, 50-56). The patch is packaged (col.4, line 1; col.18, lines 45-47). The therapeutic formulation is hydrogel that comprises local anesthetic such as lidocaine, and polymer such as

polyvinyl pyrrolidone (col.4, lines 13-15, 28, 45; col.7, lines 1-2; col.11, lines 43-45). The patch further comprises alcohol, which reads on the preservative (col.6, line 6). The lidocaine is present in that the amount of 0.5-4% (col.5, lines 13-15).

US '227 does not teach that the patch is sterile, the amount of PVP, the patch is sterile or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59). The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '227 and select the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

9. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGBP 2003/0027833 ('833) in view of US '071.

PGPB '833 teaches a method and a delivery system for administration of at least one local anesthetics agent to a patient by applying the delivery system to the skin (abstract; page 2, 0017, 0019). The drug delivery device comprises a backing layer laminated to a drug reservoir (page 2, 0023; page 8, 0088). The reservoir comprises a hydrogel comprising hydrophilic polymers comprising polyvinyl pyrrolidone (page 6, 0070, 0071; page 8, 0086; page 9, 0091). The reservoir comprises the local anesthetic and a preservative (page 8, 0083). The backing layer is preferably breathable and made of polyester or polyether (page 9, 0092). The preferred local anesthetic is lidocaine (page 4, 0048).

PGPB '833 does not teach the patch is sterile and packaged, or the amount of the anesthetic and PVP, or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

The amounts of different ingredients and specific species are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59).

The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '833 and select the amount of the anesthetic according to specific patient need and the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615
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PATENT EXAMINER